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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LIEU, JULIE BICHNGOC	

ART UNIT	PAPER NUMBER
2636	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/746,294	STRODA ET AL.	
	Examiner	Art Unit	
	Julie Lieu	2636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-29 and 31-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31* is/are allowed.

6)☒ Claim(s) *7-30 and 32-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is in response to amendment filed May 13, 2005. Claims 7-9, 11, 28, and 36 have been amended.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, it is not clear which patient, first or second, "the patient" refers to?

Claim Rejections - 35 USC § 102

4. Claims 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Boon (US Patent No. 5,796,059).

Claim 11:

Boon discloses a system for monitoring a patient, comprising:

a. A pressure pad for providing a signal indicating a pressure condition;

b. A control unit (40, 56, 58, and sensing electrodes) connected to the pressure pad and responsive to the signal; and

c. A casing 52 at least partly encasing the controller unit and at least partly encasing the pressure pad.

Claim 12:

The pressure pad in Boon is activated by removal of pressure and inactivated by application of pressure.

Claim 32:

Boon discloses an alarm means activated by said signal indicating a pressure condition.

Claim 36:

Boon discloses a system for monitoring a patient, comprising:

a. A pressure sensor for providing a signal indicating a pressure condition;

b. An alarm means (fig. 3) connected to the pressure sensor and responsive to the signal; and

c. A casing 52 defining an interior, at least a portion of the control unit (40, 56, 58, and sensing electrodes) and at a portion of the pressure pad being position in the interior of the casing.

Claim Rejections - 35 USC § 103

5. Claims 7-10 are rejected under 35 U. S. C. 132(a) as being unpatentable over Cross (US Patent No. 5,494,046) in view of Boon (US Patent No. 5,796,059).

Claim 7:

Cross discloses a method of monitoring a patient, comprising the steps of attaching a fastener (fig. 4) to the patient, wherein if the patient moves beyond a predetermined distance, a switch moves between one of an open state of a closed state to the other of the open and closed state. Cross fails to discloses placing pressure pad under the patient that activates a switch when energize. However, such concept is old and well known in the art as taught in Boon. Therefore, it would have been obvious to one skilled in the art to combine the system taught in Boon into the system in Cross because it would further enhance the detection of the system. Cross provides an alarm signal when the first switch is activated, that is when a patient is moved beyond a predetermined distance. One skilled in the art would have readily recognized providing an alarm signal in this combined system when the pressure on the pressure pad is removed. Moreover, the one skilled in the art would have readily recognizing communicating the control unit of the combined system with the first and second switches to provide an alarm in response to one or both of the switches of the combined system.

Claim 8:

The fastener is attached to the clothing of the patient in Cross. See fig. 4.

Claim 9:

Cross teaches the step of providing a verbal message to the patient.

Claim 10:

Cross also teaches the step of transmitting a signal to a remote station and providing an alarm to a caretaker at the remote station.

Claim Rejections - 35 USC § 103

6. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Cross (US Patent No. 5,494,046)

Claim 13:

Boon fails to disclose a recorded voice message sounding within hearing distance of the patient. Nonetheless, such feature is conventional in the art as taught in Cross wherein the voice alarm in located near the station. In light of this teaching it would have been obvious to one skilled in the art to provide a verbal warning device within the hearing distance of the system in Boon for the same purpose as in Cross.

Claim 14:

In Boon, the pressure pad responds to pressure by reducing electrical resistance between a first point and a second point. The apparatus including a switch armed upon the reduction of electrical resistance and an alarm for providing the alarm when the switch has been armed and the electrical resistance is under a predetermined resistance threshold, wherein a movement of the patient from the pressure pad triggers the alarm. Col. 3, third paragraph to col. 4, first paragraph. A time delay, such as 1 second, is not disclosed in Boon, but the concept of using time delay to avoid false alarm is conventional in the art, as taught in Cross. Therefore, it would

have been obvious to one skilled in the art to use a time delay in the Boon system to prevent false alarm caused by inadvertent movement of the patient.

Claim 15:

The alarm in Boon provides the alarm when the switch has been armed and electrical resistance is under the predetermined resistance threshold. Regarding the time delay between 2 seconds and 3 seconds in duration, it is not disclosed in Boon, but the concept of using time delay to avoid false alarm is conventional in the art as taught in Cross. Therefore, it would have been obvious to one skilled in the art to use a time delay in the Boon system to prevent false alarm caused by inadvertent movement of the patient.

7. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Smith, III (US Patent No. 3,737,930).

Claim 17:

Boon disclose an a pressure pad comprising an alarm system having a pressure switch 12, 14, the alarm being connected to the switch, and being armed upon the pressure being placed on the pressure pad and activated upon a release of pressure of the pressure removed. Boon fails to disclose a gel cushion. Nonetheless, the use of gel cushion to provide resting comfort to patient is conventional in the art as shown in Smith, III. Therefore, it would have been obvious to one skilled in the art to use a gel cushion with the system in Boon, by placing it on top of the pressure sensing device because it provides comfort while pressure on the gel cushion would also result in pressure on the pressure switch.

Regarding the claimed preventing activating the alarm when the pressure has been on the pad for more than a predetermined time and the release of the pressure are separated in time more than a preset period of time, it would have been obvious to one skilled in the art to consider some time delay because false alarm would be preferably avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when nursing personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of the patient on the bed would cause false alarm to go off.

Claims 18 and 19:

The alarm in Boon is audible. Nonetheless, the use of a visible/audible/tactile alarm is conventional in the art and would not present an inventive step. Therefore, one skilled in the art can use an audible or visual, or a combination thereof as desired because they are functionally equivalent and also the function of the device would not thereby be modified.

Claim 20:

The pressure switch in Boon includes two conductors spaced by a flexible material that permits contact between the conductors under a predetermined amount of pressure.

8. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Cross (US Patent No. 5,494,046) and Triplett et al. (US Patent No. 4,175,263).

Claims 21-23:

Boon discloses a method of monitoring a patient, comprising the steps of:

a. Placing a pressure pad (including 52) on a resting place, a bed or a chair, for the patient;

b. Energizing the pressure pad, whereby a signal is provided responsive to pressure more than a predetermined pressure being placed on the pressure pad by the patient (a minimum pressure that causes the detection);

c. Applying pressure above the predetermined pressure to the pressure pad (patient lying on the pad);

d. Removing the pressure above the predetermined pressure;

e. Arming the pressure pad when the pressure more than a predetermined pressure a predetermined weight the detection is on the pressure pad whereby the pressure pad serves as a sensor;

f. Activating an alarm when the predetermined pressure has been on and then is removed from the armed pressure pad

g. Disposing of the pressure pad when the patient no longer has use of the pressure pad.

Regarding the claimed preventing activating the alarm when the pressure has been on the pad for more than a predetermined time and the release of the pressure are separated in time more than a preset period of time, it would have been obvious to one skilled in the art to consider some time delays, such as that in Cross, because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when nursing personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing

false alarm to go off. Further, one skilled in the art would have readily recognized that the situation wherein the pressure has been applied on the pad for some time and removed from the pad for some time would most likely a situation that the patient is actually using the pad and left the pad. Therefore, one skilled in the art would apply such concept into the Boon system because it would prevent false alarms.

The reference fails to disclose disposing the first pressure pad and replacing with the second pressure pad. However, it would have been obvious to one skilled in the art to make the pressure pad in the combined system of Cross and Boon disposable as desired and replacing the disposable pad with a new one for use by another patient for sanitary reasons. This claimed feature only presents an obvious choice, not an inventive step because the function of the device would not thereby be modified.

Boon fails to disclose a second sensor placed in juxtaposition with the patient. However, Triplett et al. teaches the use of a second sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or moving direction as the patient tries to leave the bed, an alarm signal is given and a monitoring station activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1 in Triplett. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care taker remote from the patient's location of the patient's dangerous position. The second sensor used in Triplett is used for detecting the direction of motion of the patient (abstract) and is a mechanical switch. The claimed second sensor being photoelectric or any other type of sensors would not constitute an inventive step because a skilled artisan would have readily recognized

using the different type of sensors as a second sensor depending on the feasibility, availability, and cost. Lacking any criticality as to why a photoelectric sensor must be used, how it would solve any stated problem, or produce any unexpected result, the mechanical switch in Triplett would be functionally equivalent as a photoelectric sensor.

9. Claims 24- is rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Cross (US Patent No. 5,494,046) and Ulrich et al. (US Patent No. 5,699,038).

Claim 24:

Boon discloses a method of monitoring a patient, comprising the steps of:

a. Placing a pressure pad (including 52) on a resting place, a bed or a chair, for the patient;

b. Energizing the pressure pad, whereby a signal is provided responsive to pressure more than a predetermined pressure being placed on the pressure pad by the patient (a minimum pressure that causes the detection);

c. Applying pressure above the predetermined pressure to the pressure pad (patient lying on the pad)

d. Arming the pressure pad when the pressure more than a predetermined pressure a predetermined weight the detection is on the pressure pad whereby the pressure pad serves as a sensor;

e. Activating an alarm when the predetermined pressure has been on and then is removed from the armed pressure pad

f. Disposing of the pressure pad when the patient no longer has use of the pressure pad.

Regarding the claimed time delay, it would have been obvious to one skilled in the art to consider some time delays, such as that in Cross, because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when an attending personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off. Further, one skilled in the art would have readily recognized that the situation wherein the pressure has been applied on the pad for some time and removed from the pad for some time would most likely a situation that the patient is actually using the pad and left the pad. Therefore, one skilled in the art would apply such concept into the Boon system because it would prevent false alarms.

Regarding the claimed microprocessor, flag, and paths, a skilled artisan would have readily recognized using a microprocessor as one in Ulrich to perform the method described in Boon because it is old and advantageous since a microprocessor can perform more function than a simple control circuit. Programming paths and flags used in a microprocessor program are conventional in the art.

Claim 25:

Boon discloses a method of monitoring a patient, comprising the steps of:

a. Placing a pressure pad (including 52) on a resting place, a bed or a chair, for the patient;

b. Energizing the pressure pad, whereby a signal is provided responsive to pressure more than a predetermined pressure being placed on the pressure pad by the patient (a minimum pressure that causes the detection);

c. Applying pressure above the predetermined pressure to the pressure pad (patient lying on the pad)

d. Arming the pressure pad when the pressure more than a predetermined pressure a predetermined weight the detection is on the pressure pad whereby the pressure pad serves as a sensor;

e. Activating an alarm when the predetermined pressure has been on and then is removed from the armed pressure pad

f. Disposing of the pressure pad when the patient no longer has use of the pressure pad.

Regarding the claimed time delay, it would have been obvious to one skilled in the art to consider some time delays, such as that in Cross, because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when an attending personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off. Further, one skilled in the art would have readily recognized that the situation wherein the pressure has been applied on the pad for some time and removed from the pad for some time would most likely a situation that the patient is actually using the pad and left the pad. Therefore, one skilled in the art would apply such concept into the Boon system because it would prevent false alarms.

Regarding the claimed microprocessor program and program flag, a skilled artisan would have readily recognized using a microprocessor as one in Ulrich to perform the method described in Boon because it is old and advantageous since a microprocessor can perform more function than a simple control circuit. Programming flags used in a microprocessor program are conventional in the art.

10. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Triplett et al. (US Patent No. 4,175,263).

Claim 26:

Boon fails to disclose a second sensor. However, Triplett et al. teaches the use of a sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or a moving direction initiated by the patient trying to leave the bed, as indicated by the second sensor, an alarm signal is given and a monitoring station activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1 in Triplett. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care giver remote from the patient's location of the patient's dangerous position. The second sensor used in Triplett is a mechanical switch.

11. Claims 27-29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059) in view of Triplett et al. (US Patent No. 4,175,263).

Claims 27 and 28:

Boon discloses a system for monitoring a patient, comprising:

a. A pressure pad for providing a signal indicating a pressure condition;

b. A control housing (inherent, housing 56, 58) connected to the pressure pad and responsive to the signal;

c. A casing 52 at least partly encasing the pressure pad.

Boon fails to disclose the casing at least partly encasing the control housing. However, it would have been obvious to one skilled in the art to encase the control housing in casing 52 because the function of the device would not thereby be modified. The shift of location of parts would not constitute an inventive step but a design choice.

Boon fails to disclose a second sensor placed in juxtaposition with the patient. However, Triplett et al. teaches the use of a second sensor 32 placed in juxtaposition with the patient so that when the patient assumes a dangerous position or moving direction as the patient tries to leave the bed, an alarm signal is given and a monitoring station activated when the alarm signal is provided, and a voice message is announced near the patient. Fig. 1 in Triplett. In light of this teaching, it would have been obvious to one skilled in the art to combine the features taught in Triplett in the system of Boon because it would further provide information to the care-giver remote from the patient's location of the patient's dangerous position. The second sensor used in Triplett is used for detecting the direction of motion of the patient, such as patient's attempt to leave a location (abstract).

Claim 29:

Boon discloses a system for monitoring a patient, comprising:

a. A pressure pad for providing a signal indicating a pressure condition;

b. A control housing (inherent, housing 56, 58) connected to the pressure pad and responsive to the signal;

c. A casing 52 at least partly encasing the pressure pad;

d. An alarm means at least partly within the casing (that is, its associated circuitry)

e. Control means within the control housing for activating an alarm when a pressure above a predetermined pressure is removed from an armed pressure pad.

Boon fails to disclose the casing at least partly encasing the control housing and the alarm. However, it would have been obvious to one skilled in the art to encase the control housing and the alarm in casing 52 because the function of the device would not thereby be modified. The shift of location of parts would not constitute an inventive step but a design choice.

Regarding the claimed time delay, it would have been obvious to one skilled in the art to consider some time delays, such as that in Cross, because false alarm would be preferable avoided and alarm should only be given during actual use of the pressure, whereas unintentional activation of the alarm could happen such as when an attending personnel might happen to press against the pad while setting up the bed for patient to use or inadvertent movement of patient on the bed causing false alarm to go off. Further, one skilled in the art would have readily recognized that the situation wherein the pressure has been applied on the pad for some time and removed from the pad for some time would most likely a situation that the patient is actually using the pad and left the pad. Therefore, one skilled in the art would apply such concept into the Boon system because it would prevent false alarms.

Regarding the claimed microprocessor program and program flag, a skilled artisan would have readily recognized using a microprocessor as one in Ulrich to perform the method described in Boon because it is old and advantageous since a microprocessor can perform more function than a simple control circuit. Programming flags used in a microprocessor program are conventional in the art.

12. Claims 32-35 and 37-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boon (US Patent No. 5,796,059).

Claim 32:

The control unit in Boon includes an alarm means activated by the signal indicating a pressure condition.

Claim 33:

Boon does not show a battery within the casing. However, it would have been obvious to power the device with battery and include it within the casing as desired because the use of battery as an alternative power supply in place of household power supply is conventional in the art and safe to use.

Claim 34:

At least one of the pressure pad and battery in Boon are at least adjacent to the alarm means in Boon.

Claim 35:

The casing in Boon is flexible. It is not clearly stated that it is waterproof. However, it would have been obvious to one skilled in the art to use waterproof casing for the device in Boon because it would protect the device from external conditions.

Claims 37-39:

The rejection of claims 37-39 recites the rejection of claims 33-35.

Claim 40:

Boon discloses a system for monitoring a patient, comprising:

a. A pressure sensor for providing a signal indicating a pressure condition;

b. An alarm means (fig. 3) connected to the pressure sensor and responsive to the signal; and

c. A casing 52 at least partly encasing and sealed around the pressure sensor.

The control unit in Boon is outside of the casing. However, it would have been obvious to include the control unit within the casing in Boon as desired because the shift of the location of the part would not thereby modify the function of the device.

Claim 41:

Boon does not show a battery within the casing. However, it would have been obvious to power the device with battery and include it within the casing as desired because the use of battery as an alternative power supply in place of household power supply is conventional in the art and safe to use.

Claims 42-44:

The rejection of claims 42-44 recites the rejection of claims 33-35.

Allowable Subject Matter

13. Claim 31 is allowed.

Response to Applicant's Remarks

14. Applicant's arguments filed 8/30/04 have been fully considered but they are moot in view of new ground of rejection.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Lieu whose telephone number is 571-272-2978. The examiner can normally be reached on MaxiFlex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Hofsass can be reached on 571-272-2981. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Julie Lieu
Primary Examiner
Art Unit 2636

Aug. 16, 05